Eurofins Viracor BioPharma

Immunotherapy Force Multiplier

It was October 2015 when the US immunotherapy market was celebrating its first-ever FDA-approved oncolytic virus therapy, talimogene laherparepvec (T-VEC). Developed by Amgen, this new genre of immunotherapy demonstrated immense efficacy in treating advanced melanoma. But being an early bird in the industry, there were severe concerns regarding the biodistribution and viral shedding from the safety perspective. Additionally, it faced challenges in the trials in terms of the sample types and volumes needed for the testing. Functioning behind the scenes here, in facilitating the launching of T-VEC and navigating through the complexities, was the US-based company, Eurofins Viracor BioPharma, an integrated arm of Eurofins that offered its laboratory services to Amgen for assays development and testing. They executed both efficacy and safety type testing to mitigate the prevailing challenges and significantly enhanced the ability to interpret clinical data from the research. "The combination of services that we provided was instrumental to Amgen's T-VEC clinical trial and ultimately contributed in its approval as the first oncolytic virus therapy in US," mentions Scott Mattivi, President of Eurofins Viracor BioPharma.

Eurofins Viracor BioPharma has been a cornerstone in the clinical research realm, offering prolific services for complex testing and assay development with over 30 years of industrial experience. Their core areas of expertise include molecular and immunological assays, specifically immunogenicity, immunological responses, and hypersensitivity, supporting clinical trials for infectious disease and oncology therapeutic development. "The scientific expertise, technological capabilities and industry-leading platforms we can bring to the table; together with the top-notch service levels we provide, enables us to address many of the prevailing bioassays and testing challenges in drug development today," mentions Scott.

Eurofins Viracor BioPharma also leverages its vast network of Eurofins partner laboratories and scientists beyond the in-house expertise to cater to diverse client needs. This helps them deeply focus on the client requirements and align their efforts to meet them. "The Eurofins global network in itself, in addition to Viracor, has been an added value for the clients, in cases where their needs cannot be met with the internally available expertise, scientists and facilities," adds Scott.

Another area Eurofins Viracor BioPharma has more recently become entrenched is the oncology space. Though new therapeutic technologies have been discovered for treating cancer patients, there remain several challenges in developing and implementing suitable bioassays to assess factors like distribution, safety, and immunogenicity. This is primarily due to the complex interaction of the immune system and tumors, and it's where Viracor has extended its services for gene and cell therapy development, focusing on genomic profiling and cell-based assays.

Scott Mattivi

The company's true strength lies in their dedicated team of experienced scientists, adept in the space of assays development, with validation expertise across multiple specimen types and technology platforms. They eliminating limitations for their clients related to sample type and analytical method. They also facilitate investigating the impact of the therapy on different areas to help meet the client's needs more completely. "This agility is not very common among our competitors. We have the capability to perform assays on multiple sample types and be platform agnostic," adds Scott.

Further, the company's recent introduction of genomic profiling services in the immuno-oncology space can help clients design more targeted and effective therapies based on the genetic makeup of the patients. The company has partnered with Illumina, the prominent biotechnology company, to introduce a next-generation sequencing service, PanCancerIQ™ that facilitates comprehensive genomic profiling of tumor samples. It leverages the Illumina TSO500 assay system that was validated in the Eurofins Viracor BioPharma facility. This assay

> **The scientific expertise, technological capabilities and industry-leading platforms we can bring to the table; together with the top-notch service levels we provide, enables us to address many of the prevailing bioassays and testing challenges in drug development today**

simultaneously measures hundreds of genomic biomarker variants (both DNA & RNA) and identifies oncogenic driver events that can forecast responses or resistances to treatments, thereby accelerating clinical development. The company also engages in digital droplet PCR (ddPCR), flow cytometry, and ELISpot that are crucial technologies deployed in the space of Immuno-oncology precision therapy development today.

Eurofins Viracor BioPharma also partnered with Moderna for clinical trial testing for the COVID-19 vaccine in the wake of the pandemic. Moderna required specific validated assays for their trial, and for this, the

company provided their highly sensitive qPCR assay. The Eurofins Viracor laboratory team performed over 2000 Phase II tests and more than 85,000 tests to support their extensive Phase III trials of 30,000 plus subjects. They succeeded in providing accurate testing with fast turnaround time. "We were able to ramp up capacity in a timely manner with accurate testing to support a trial of this size, which led to the emergency use authorization of the vaccine candidate by the US FDA," adds Scott. This also helped Moderna keep pace with market competition and contribute to bringing the much-needed vaccine, extremely important at that stage of the pandemic. Along with testing for clinical trials, the company has helped clients to overcome the challenges of enrollments for non-COVID trials by helping support them with supply chain difficulties, reagent supplies, and specimen transport logistics. The company's extensive network of laboratories and interconnectivity with other organizations assisted them in meeting the shortages and gaps in testing.

With a positive stance towards the future, Eurofins is working toward expanding its laboratory footprint. They are constructing a purpose-built facility that will nearly double their footprint, which is expected to open in Q1 of 2022 and allow additional testing platforms and better access to key logistics. The company is keen on leveraging the global footprint of the Eurofins organization. Beyond the construction of the new facility, they have also purchased additional property that will allow for a subsequent increase of the new footprint by 50 percent, and they aim to expand it more by 55,000 sq feet post the Q1 of 2022.